In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-109V

Filed: November 13, 2023

* *

FRANCES RUZICKA,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

Patricia Finn, Patricia Finn, P.C., Nanuet, NY, for Petitioner
Sarah Rifkin, U.S. Department of Justice, Washington, DC, for Respondent

DECISION ON ENTITLEMENT[1]

Oler, Special Master:

On January 24, 2017, Frances Ruzicka ("Petitioner" or "Ms. Ruzicka") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] (the "Vaccine Act" or "Program"). The petition alleges that Ms. Ruzicka developed fibromyalgia and "post-vaccination syndrome" as a result of the tetanus, diphtheria, and acellular pertussis ("Tdap") vaccine she received on July 29, 2014. Pet. at 1, 6, ECF No. 1.

[1] Because this Decision contains a reasoned explanation for the action in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Upon review of the evidence in this case, I find that Petitioner has not established by preponderant evidence that the Tdap vaccine can cause or did cause her symptoms. The petition is accordingly dismissed.

I. Procedural History

Ms. Ruzicka filed her petition on January 24. 2017. Pet. at 1. She filed medical records in support of her petition on February 16, 2017 (Exs. 1-4) and April 19, 2017 (Ex. 6).[3] Respondent submitted his Rule 4(c) Report on September 22, 2017, recommending that "entitlement to compensation be denied" in this case. Resp't's Rep. at 1, ECF No. 20. In his Rule 4(c) Report, Respondent requested that Petitioner file medical records related to "any rheumatological assessments prior to her vaccination" at issue in this case. *See* ECF No. 20 at 1, n. 1.

I held a status conference on September 4, 2018. Respondent articulated reasonable basis concerns for this claim, stating that it was his position that "post-vaccination syndrome" was not a recognized injury under applicable case law. Respondent was also unsure as to how an aluminum adjuvant theory of causation, as proposed by Petitioner's potential expert in this case, Dr. Yehuda Shoenfeld, would be different from an autoimmune/inflammatory syndrome induced by adjuvants (ASIA) theory -- i.e., a theory that has been strongly criticized by special masters in prior Vaccine Act cases. Petitioner's counsel stated that, although she had alerted her client about the need to produce additional medical records that were requested by Respondent in his Rule 4(c) Report filed on September 22, 2017, she had been unsuccessful in retrieving those records as of the date of the status conference. After the conference, I ordered Petitioner to file an expert report, as well as the outstanding records requested by Respondent in his Rule 4(c) Report. Scheduling Order dated September 4, 2018; ECF No. 33.

Petitioner filed an expert report from Dr. Toni Bark on January 25, 2019. Ex. 6, ECF No. 36. Respondent filed responsive expert reports on September 30, 2019, from Drs. Arnold Levinson and Carlos Rose. Exs. A, C.

On October 29, 2019, I ordered Petitioner to file any prior rheumatology records. Non-PDF order dated October 29, 2019. I reiterated this same order on January 2, 2020. *See* Non-PDF Order dated January 2, 2020. On February 27, 2020, Petitioner filed a status report, indicating that no additional prior rheumatology records existed. ECF No. 48.

On April 2, 2020, Petitioner filed a status report informing the Court that Dr. Bark had passed away on March 2, 2020. ECF No. 49. Petitioner requested an extension of time to locate a new expert. *Id.* I granted that request.

On September 3, 2020, Petitioner filed an expert report from Dr. James Lyons-Weiler. Ex. 23. On December 8, 2020, Respondent filed a Motion to Exclude Dr. Lyons-Weiler's Report. ECF No. 62. I held a status conference on December 14, 2020, to discuss Respondent's motion. *See* Minute Entry dated 12/16/2020; Scheduling Order dated 12/16/2020. During the status conference,

[3] The page numbers in all of the medical record exhibits have two different page stamps. For consistency, I have referenced the number in the bottom middle of the page throughout this Decision.

Petitioner's counsel indicated she intended to file a motion to strike Dr. Lyons-Weiler's report and that she was in the process of securing a different expert. Scheduling Order dated 12/16/2020, ECF No. 65. I indicated that Dr. Lyons-Weiler's report would remain in the record for the purpose of determining fees, however I would not consider it as evidence pertaining to entitlement; the parties agreed. *See id.*

On February 15, 2021, Petitioner filed an expert report from Dr. James Neuenschwander. Ex. 49. The parties then filed a series of responsive expert reports. Exs. 63, 79, E, F, H, I.

The parties filed their respective motions for a ruling on the record and confirmed that the record is complete. ECF Nos. 87, 88, 89.

On September 26, 2023, I admitted Court Exhibit 1001, which is described below:

On September 5, 2017, Dr. Neuenschwander posted the following comment on WordPress, a blog hosting platform:

> Nowhere else in medicine do we do what we do with vaccines, where we give everybody that exact same dose of something. And then we're shocked that we get some bad outcomes. And we have a vaccine injury court that paid out $3.6 billion, last I checked, for vaccine injuries.
>
> And when you look at what these vaccine injuries are, most of them are all symptoms of autism… encephalopathy, seizures, and things along those lines… and what am I supposed to think? I'm supposed to tell parents that, regardless of their knowledge, they should vaccinate, just because everyone tell [sic] me to?
>
> I can't abide by that. I mean, there has to be a way for us to say, these are children at risk and they just shouldn't be vaccinated. And because of my experience, I've been doing this for a long time, I've gone from being that vaccine Nazi to being somebody who… I don't know if there's a vaccine I would recommend anymore.
>
> — James Neuenschwander, MD

Court Ex. 1001.

I gave Petitioner until October 26, 2023 to file a response to Court Exhibit 1001. *See* Scheduling Order dated September 26, 2003; ECF No. 103. Petitioner did not file a response.

This matter is now ripe for an adjudication.

II. Medical Records

A. Relevant Pre-Vaccination History

Petitioner was 51 years old when she received the Tdap vaccination on July 29, 2014. *See* Ex. 4 at 1. She had a long history of joint pain, "diffuse myalgias," irritable bowel syndrome ("IBS"), asthma, and hypothyroidism. *See* Ex. 2 at 10, Ex. 3 at 32.

Prior to vaccination, on June 20, 2014, Petitioner called her doctor's office to get a note exempting her from Tdap vaccine because of a prior reaction she had to the diphtheria-tetanus-pertussis ("DTP") vaccine "years ago." Ex. 2 at 7. Petitioner said she had experienced nausea, diarrhea, sore joints, and itchy skin when she last received the DTP vaccine. *Id.* The reaction had lasted for a few days. Ex. 3 at 21. Dr. Bobek wrote the following note: "Frances A. Ruzicka is a 51-year-old patient of mine who says that years ago she had a 'DPT' shot and got sick from it…. Because of this reaction, I ask that Ms. Ruzicka not be required to have a Tdap vaccination." Ex. 2 at 9. Petitioner's employer denied the request. Ex. 5 at 3.

Petitioner received a Tdap vaccine on July 29, 2014. Ex. 4 at 1. She emailed her employer on the same day stating, "I am going to receive this vaccine today against my better judgment. In the event of any adverse reaction as I have had in the past, I will hold the employer solely responsible." Ex. 6 at 6.

B. Post-Vaccination History

On August 4, 2014, Petitioner presented to Dr. James Joseph at Geisinger Elysburg Family Practice, regarding redness and warmth in her right arm, and reported it was painful, heavy, and tight. Ex. 2 at 10. She also reported feeling nauseous. *Id.* Petitioner was diagnosed with cellulitis, and was instructed to rest and was given Zithromax, an antibiotic. *Id.* at 11.

On September 10, 2014, Petitioner returned to Geisinger Elysburg Family, and was seen by Dr. Francis Bobek, her primary care physician ("PCP"). Ex. 2 at 18. Dr. Bobek's summary of Petitioner's prior history is as follows:

> The patient has not felt well since she had a Tdap vaccination on Jul 29 2014 in the right deltoid area. The patient missed work on Jul 30, 31 and August 1 because of not feeling well after the vaccination. The patient had headache sore throat and joint pains. The patient was seen by my associate on August 4 because of a red warm swollen tender right shoulder. She was diagnosed as cellulitis and reaction to vaccination. The patient was treated with azithromycin and her warm red swollen shoulder resolved.
>
> However the patient has continued to have intermittent problems which include pains in the joints. She currently is bothered by pains in the elbows wrists shoulders and hips. She says she feels pain in the bilateral greater trochanteric areas of the hips. She has also had a headache on and off since … vaccination. In the last few days she has developed tingling in the hands and feet bilaterally. She … also noticed worsening of her headache which is mostly in the neck and occipital area…. The patient feels very stressed because of the persistence of symptoms since the vaccination.

Id. at 18-19. On physical examination, Dr. Bobek noted "bilateral point tenderness in the lateral epicondylar areas. She has tenderness with palpation of the bilateral trochanteric bursa areas. She has pain deep in the deltoids with internal external rotation of the shoulders bilaterally. The joints are not red warm or swollen." *Id.* at 20. Dr. Bobek diagnosed Petitioner with a "post-vaccination reaction" and elevated blood pressure and paresthesias and recommended Petitioner return for a follow-up in a week. *Id.* at 21.

On September 17, 2023, Petitioner returned to discuss her symptoms and bloodwork results with Dr. Bobek. Ex. 2 at 44. Petitioner's thyroid-stimulating hormone ("TSH") was elevated; Petitioner informed Dr. Bobek "that she had head pounding in the past when she was on higher doses of thyroid medicine years ago. Because of that side effect she discontinued the thyroid medicine and, per her personal report, has been hypothyroid for least 10 years. The patient is willing to try a low dose of thyroid replacement therapy." *Id.* Dr. Bobek also noted in the "Post vaccination syndrome" section, that Petitioner's right shoulder swelling and redness had resolved but Petitioner had increased "skin and muscle sensitivity in her proximal upper and lower extremities and torso." *Id.* Petitioner reported a "fire-like" sensation when running her hands over the skin of her extremities and torso. *Id.* Petitioner reported a history of numbness and tingling in her hands and feet. *Id.* at 47. On physical exam, Dr. Bobek noted Petitioner had some pain with palpations of the arm muscles as well as thigh muscles and abdominal and back muscles, and that Petitioner was angry that her symptoms developed post vaccination and was anxious about worsening symptoms in the future. *Id.* Dr. Bobek listed hypothyroidism as the primary encounter diagnosis, but included "serum reaction due to vaccination" and paresthesia, and prescribed Petitioner levothyroxine[4] and prednisone. *Id.*

On October 2, 2023, Petitioner messaged Dr. Bobek for a neurology consult. Ex. 2 at 69-70. On October 4, 2014, Petitioner and Dr. Bobek met to follow up on her ongoing issues. *Id.* at 72. Petitioner's latest symptoms included chronic sore throat, persistent bilateral torso pain, chronic left greater than right ankle joint pain, and transient swelling and discoloration of the left ankle, continued paresthesias in the thighs, left hand numbness while driving, impaired sleep, increased acid reflux, transient chest heaviness, and chronic anxiety. *Id.*

On November 3, 2014, Petitioner returned to Dr. Bobek for a follow up. Ex. 2 at 86-89. Petitioner was resistant to increasing her thyroid medications, but Dr. Bobek warned that her untreated hypothyroidism could complicate her symptoms and lead to neurologic, psychiatric, metabolic, and orthopedic issues. *Id.* at 86. Petitioner agreed to increase her levothyroxine dosage. *Id.* Petitioner reported "migratory sharp pains and paresthesias in [her] arms and legs," including a shooting pain sensation when she turned a doorknob, as well as swelling in her ankles that comes and goes. *Id.* Petitioner refused treatment for her anxiety despite biting her nails and fingers. *Id.* On physical examination, Petitioner had "some tenderness with palpation of the ulnar groove in

[4] Levothyroxine sodium: the monosodium salt of l-thyroxine, the naturally occurring form of thyroxine, obtained from the thyroid gland of domesticated food animals or prepared synthetically. It is used as replacement therapy for hypothyroidism and in the prophylaxis and treatment of goiter and of thyroid carcinoma, administered orally, intramuscularly, or intravenously. DORLAND'S MEDICAL DICTIONARY ONLINE, www.dorlandsonline.com/dorland/definition?id=28172&searchterm=levothyroxine+sodium (last visited Aug. 8, 2023) ("DORLAND'S").

the medial left elbow area." *Id.* at 88. Dr. Bobek recommended following up in three months. *Id.* at 89.

On November 5, 2014, Petitioner presented to Geisinger-Bloomsburg Hospital for a neurology consult. Ex. 3 at 3-4. She was seen by Dr. Joseph Alario, D.O., a neurology resident, who dictated notes from this appointment, and Dr. Uzzal Roy, M.D., a neurologist, who observed. *Id.* at 7. Dr. Alario's note consisted of the following observations: "chief complaint of muscle soreness and abnormal pain sensation and her history and physical exam [] may be a post vaccination syndrome, but with low thyroid may have prolonged recovery, no evidence of a central nervous system process and normal ANA and ESR are reassuring. The complaints of shooting pain in her elbows is concerning for left ulnar neuropathy." *Id.* at 6. Petitioner's neurological exam was largely normal. *Id.* at 6. It was recommended that Petitioner follow up in three months or call if any symptoms worsened.

On January 5, 2015, petitioner saw Dr. Todd Preston, an otolaryngologist. Ex. 3 at 21. She reported a sore throat with globus sensation, dry cough, and hoarseness that started five months ago after she received a Tdap vaccine. *Id.* Dr. Preston assessed Petitioner with "[n]ew onset of GERD symptoms unlikely related to vaccination." *Id.* at 23. He further stated that "It is extremely unlikely for this pt to be suffering from post-vaccination reaction 6-7 mo after injection, and almost impossible for this to be related to GERD lesions. [With] the host of systemic symptoms, a systemic process is more likely." *Id.*

Petitioner was seen by Dr. Alfred Denio, M.D., a rheumatologist, on January 20, 2015. Ex. 3 at 31-33. Petitioner was referred to Dr. Denio by Dr. Bobek for her "diffuse arthralgias, myalgias, and paresthesias." *Id.* at 31. It was Dr. Denio's impression that Petitioner had fibromyalgia, and that it was "fairly typical by history and physical, appears to have been triggered by a reaction to a Tdap vaccine last July…. In reviewing her previous history, she has had episodes of diffuse discomforts over the years. No indication of a Guillain-Barre or other radiculopathy as her neurologic exam is normal. No evidence of an inflammatory arthritis. She seems to be under a lot of stress currently." *Id.* Dr. Denio noted that Petitioner's fibromyalgia "appears to have been triggered by a reaction to a Tdap vaccine last July." *Id.*

On March 25, 2015, Petitioner saw neurologist, Dr. Scott Friedenberg at Geisinger Neurology. Ex. 3 at 53-54. Dr. Friedenberg noted that Petitioner had a history of:

> many years of multiple multifocal neurologic symptoms without etiology identified, sx ppt by recent vaccine? And her flare ups of disease are short lived in past, with vaccination sx have persisted.
>
> Pt with clinical history of fibromyalgia based on normality of clinical exam and significance of myofascial pain. Continues with joint sx, muscle aches, numbness, fatigue. Finds she has trouble at work with opening bags. After day of work she is very sore and fatigued, wants to be away from people (reports leaving her grandsons birthday party due to discomfort and despondence about her sx).

Id. at 53. It was Dr. Friedenberg's impression that Petitioner had fibromyalgia and recommended

a trial of medication to which Petitioner stated "I'm not a pill taker and I won't take anything." *Id.* at 54. He recommended testing for Sjogren's syndrome and small fiber neuropathy but opined, "I suspect she does not have any other diagnosis." Without additional testing, Dr. Friedenberg believed that fibromyalgia was Petitioner's diagnosis. Because Petitioner refused additional testing and treatment, Dr. Friedenberg believed he was at a standstill. *Id.* Petitioner requested a referral to a pain management clinic. *Id.*

On May 13, 2015, Petitioner returned to Dr. Bobek for her ongoing issues. Ex. 2 at 129-32. Petitioner complained of chronic pain in her ankles, knees, hips, glutes, elbows, wrist, hands, back and thighs, which Dr. Bobek classified as part of Petitioner's fibromyalgia. *Id.* at 129. These pains gave her difficulties at work. *Id.* Petitioner reported that she had stopped taking her thyroid medication in March and noticed reduced hand swelling, breast tenderness and swelling, weight gain, and nausea. *Id.*

On June 2, 2015, Petitioner went to the Gsach-Geisinger Shamokin Emergency Room for "substernal chest heaviness on and off for the last week, non-radiating, associated with dyspnea,[5] nausea, burning sensation that radiates up her chest. States 2 weeks ago she hooked herself up to the monitor… and she did not have a LBBB[6]… She is very concerned she has an ulcer." Ex. 3 at 107. Her tests and lab work indicated nothing abnormal, and she was discharged. Ex. 2 at 155-57.

She saw her PCP on June 11, 2015, to follow up on her chest pain. Ex. 2 at 155. Dr. Bobek noted Petitioner had an extensive cardiac work up and no cardiac disease was identified. *Id.* Petitioner also presented concern for her work as she was having difficulty lifting patients with her fibromyalgia pain. *Id.* She insisted that she did not take medication for either her fibromyalgia or anxiety, but was willing to receive psychological counseling. *Id.* She further denied medication for her hyper cholesterol. *Id.*

On November 25, 2015, Petitioner returned to Dr. Bobek still reporting widespread myalgias, poor sleep, muscle twitching, ankle swelling, mental sluggishness, and constant fatigue. Ex. 2 at 188.

On December 7, 2015, Ms. Ruzicka returned to Dr. Bobek for a follow-up regarding her fall from several days prior. Ex. 2 at 199-203. Petitioner reported that she had sprained her ankle falling down the stairs, and went to the emergency room for treatment. *Id.* She was given a brace and was walking with crutches, but felt like she could not bear any weight on her right ankle. *Id.* She was given a smaller ankle brace and a physical therapy referral. *Id.* at 203.

---

[5] Dyspnea is "breathlessness or shortness of breath; difficult or labored respiration." DORLAND'S, www.dorlandsonline.com/dorland/definition?id=15277&searchterm=dyspnea (last visited Oct. 31, 2023).

[6] LBBB stands for "left bundle branch block." A bundle branch block is "interruption of conduction in one of the main bundle branches [of the heart], left or right; the sequence of ventricular depolarization is altered since the impulse reaches one ventricle and then travels to the other." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=60753 (last visited Nov. 7, 2023).

On September 10, 2019, Petitioner saw Christopher Whiting, D.O., a neurologist. Ex. 21 at 1. She reported that since her Tdap vaccination, she had experienced intermittent numbness/tingling, joint pain, muscle aches, an intermittent rash, a tendency to drop things, dry eyes, dry mouth, weakness in her legs, tinnitus, post-traumatic stress, anxiety and depression. *Id.* at 1-2. Petitioner reported that she was "not interested in taking any medications for symptoms except CBD and medical marijuana." *Id*. at 2. Petitioner's neurologic exam was entirely normal except that Dr. Whiting documented her gait and Romberg[7] as unsteady. *Id.* at 5-6. Dr. Whiting suggested that petitioner "consider a skin biopsy to rule out small fiber neuropathy." *Id*. at 7. There is no indication that Petitioner obtained the recommended biopsy.

On January 13, 2020, Petitioner visited Emily Brunner, D.O., a rheumatologist. Ex. 22 at 5. The HPI describes that Petitioner is a "57 year old female with [history] of fibromyalgia, anxiety, cyclic nausea, hypothyroidism (untreated), [hypertension] (untreated) who is referred for myalgias." *Id.* At this visit, Petitioner described "generalized pain of the muscles, joints, and nerves" for five and one half years. *Id*. She was concerned there was "something being missed" by her physicians and was further concerned that she had multiple sclerosis. *Id*. An EMG performed in 2019 was normal, and a brain MRI showed nonspecific degenerative changes. *Id*. A prior neurologist mentioned "possible small fiber neuropathy." *Id.* Dr. Brunner noted that Petitioner's blood pressure was "markedly elevated," at 210/100. *Id.* Further, her TSH level was elevated at 54.02 ulU/ml. *Id*. at 9. Petitioner indicated that her hypothyroidism was untreated and that she did not plan to take medication for it. *Id.* at 10. Dr. Brunner documented that Petitioner experienced "a chronic widespread pain with heightened pain response, and often associated with fatigue, poor sleep, IBS, and anxiety. Her current presentation is still very fitting of this diagnosis, [fibromyalgia] and do not suspect another autoimmune or inflammatory diagnosis at this time." *Id*. Finally, Dr. Brunner documented: "Presentation most consistent with FMS. Likely her symptoms are in part made worse by untreated hypothyroidism." *Id.*

No other relevant medical records were submitted.

III. Petitioner's Affidavit

Petitioner signed her affidavit on January 3, 2017. Ex. 1 at 3. Petitioner stated two days after receiving her July 29, 2014, Tdap vaccine, she called to work to request sick leave because of flu-like symptoms, sore muscles and joints, headaches, nausea and vomiting, sore throat, and soreness and redness at the injection site. *Id.* at 1.

Petitioner reported that her symptoms got worse after taking antibiotics, but her cellulitis resolved. *Id.* Petitioner mentioned that her neurological symptoms increased in frequency and duration, and numbness spread to her lower and upper extremities. *Id.* Petitioner also developed a sensitivity to touch. *Id.* at 2.

[7] Romberg sign is "swaying of the body or falling when standing with the feet close together and the eyes closed; the result of loss of joint position sense, seen in tabes dorsalis and other diseases affecting the posterior columns." DORLAND'S, www.dorlandsonline.com/dorland/definition?id=106448 (last visited Nov. 2, 2023).

Petitioner saw her PCP, Dr. Francis Bobek on September 10, 2014 out of concern for her symptoms worsening. Ex. 1 at 2. Dr. Bobek diagnosed Petitioner with "post-vaccination syndrome," which resulted in Petitioner being unable to work for 11 weeks. *Id.*

Petitioner next saw rheumatologist Dr. Alfred Denio on January 20, 2015, and was diagnosed with fibromyalgia triggered by the Tdap vaccination she received on July 29, 2014. Ex. 1 at 2. She continues to experience nausea, dizziness, insomnia, numbness and tingling in her extremities, sore muscles, joint and nerve pain, fatigue, chronic sore throat resulting in difficulty swallowing, and muscle spasms. *Id.* As a result, Petitioner cannot perform normal day-to-day activities such as holding items like a shopping bag or cellphone or opening bottles or cans. *Id.* She can only walk short distances, experiences "fibro fog," and can no longer lift heavy objects. *Id.* at 2-3.

While at work on June 5, 2015, Petitioner experienced chest pain that required her to be taken to Geisinger Medical Center, where she was informed that she experienced a heart attack and left bundle branch block. Ex. 1 at 2.

On December 3, 2015, Petitioner fell down the stairs due to numbness in her legs, which resulted in three torn ligaments in her right ankle. Ex. 1 at 2. Petitioner has missed a total of seven months of work due to her alleged vaccination injuries. *Id.* She is also only able to work a four hour shift three to four days per week. *Id.* at 3.

IV. Expert Opinions and Qualifications

A. Petitioner's Expert: Dr. Toni Bark, M.D.

Dr. Bark received a B.S. in psychology from the University of Illinois in 1981 and received her medical degree from Rush Medical College in 1986. Ex. 7 ("Bark CV") at 1. Dr. Bark completed residencies in rehabilitative medicine and pediatrics and received a M.S. in healthcare emergency management in 2012. *Id.* Dr. Bark also held a number of hospital and clinical positions over two decades and previously served as the Medical Director and owner of the Center for Disease Prevention in Evanston, Illinois. *See* Bark CV at 1-2.

Dr. Bark filed one expert report in this case. Ex. 6 (hereinafter "Bark Rep."). In her report, Dr. Bark pointed to the aluminum hydroxide component of the Tdap vaccine as the "logical cause" and as "sequentially connected to petitioner's injuries." Bark Rep. at 2. Dr. Bark stated that Petitioner had been diagnosed by her treating physician as having "a vaccine-induced Myalgic Encephalomyelitis/Chronic Fatigue Syndrome [ME/CFS] and fibromyalgia." *Id.* at 3. She elaborated on her proposed causal mechanism, opining that Petitioner suffered from "*endoplasmic reticulum (ER) HyperStress* induced autoimmunity… from a combination of genetics risk factors … coupled with environmental exposures (aluminum hydroxy), which together can cause cellular death and pathological outcomes experienced by petitioner." *Id.*

Dr. Bark opined that the endoplasmic reticulum stress leads to an accumulation of unfolded proteins, which causes a reduction of general protein translation rate, an increase in expression of endoplasmic reticulum chaperones, and the onset of protein degradation. Bark Rep. at 4. She

opined that aluminum causes ER hyperstress. *Id.* She further opined that "[a]ny environmental factors that induces [sic] ER HyperStress (TDaP) will interact with genetic ER Hyperstress, and the effects can influence both the production of molecular mimicry and deranged immune function as occurred in petitioner's case." *Id.* at 5. Dr. Bark concluded by stating "the theory of aluminum-induced ER Hyperstress as playing an important role in the petitioner's individual case of vaccine-induced autoimmunity is more likely than not the cause of the vaccine injuries she sustained and the sequala to those injuries." *Id.* at 6.

B. Petitioner's Expert: Dr. James Neuenschwander, M.D.

Dr. Neuenschwander received a B.S. in cellular and molecular biology in 1981 and his medical degree in 1985, both from the University of Michigan. Ex. 50 ("Neuenschwander CV") at 1. He also participated in three years of a general surgery residency program at the University of Michigan before voluntarily leaving to pursue an integrative medicine practice and founding Bio Energy Medical Center. *Id.* Dr. Neuenschwander is board certified in emergency medicine and certified by the American Board of Integrative and Holistic Medicine. *Id.* at 3.

Dr. Neuenschwander filed two reports in this case. Exs. 49, 63. In his first expert report, Dr. Neuenschwander disagreed with Dr. Bark regarding Petitioner's diagnosis. Ex. 49 ("First Neuenschwander Rep.") at 1. Dr. Neuenschwander opined that Petitioner's symptoms were consistent with small fiber neuropathy and fibromyalgia; not ME/chronic fatigue syndrome as posited by Dr. Bark. *Id*.

He stated that the onset of Petitioner's symptoms began with hyperesthesia, which started a few days after her severe local reaction to the Tdap vaccine. First Neuenschwander Rep at 2. Dr. Neuenschwander opined that Petitioner's initial response was not cellulitis, but instead was a "classic over-reaction of her immune system to the adjuvant in the vaccine." *Id.*

Dr. Neuenschwander opined that Petitioner suffers from small fiber neuropathy ("SFN") and fibromyalgia. First Neuenschwander Rep. at 3. Dr. Neuenschwander stated "It is likely that Francis had a significant predisposition for SFN based on her Hashimoto's history and her TDaP vaccination was the precipitating event that cause[d] her fibromyalgia and SFN pain symptoms resulting in her current state of disability." *Id*. at 4.

Dr. Neuenschwander then focused his first expert report on the connection between aluminum adjuvants and Petitioner's development of symptoms. He opined that aluminum is a neurotoxin and noted that the Agency for Toxic Substances and Disease Registry set a minimal risk level for intake of oral aluminum at 1mg/kg/day. First Neuenschwander Rep. at 4-5. He further stated that injected aluminum, unlike inhaled and IV aluminum which are eliminated quickly, forms a depot of particles in the body's tissues. *Id.* at 5. Dr. Neuenschwander stated that the oral absorption of aluminum is approximately 0.3%, while the absorption of aluminum from a vaccine is approximately 100%. *Id*. Accordingly, Petitioner's Tdap vaccine contained the equivalent of 130mg of oral aluminum, twice the minimal risk level for neurotoxicity. *Id.*

The excess aluminum from the Tdap vaccine caused Petitioner's immune system to become over activated. First Neuenschwander Rep. at 5. This overactivation led to oxidative stress.

Id. In Petitioner, this normally temporary process became chronic – or what Dr. Neuenschwander referred to as persistent oxidative stress. *Id.* at 6. Dr. Neuenschwander further opined that persistent oxidative stress plays a role in SFN and fibromyalgia. *Id.*

In his second expert report, Dr. Neuenschwander summarized his causation theory as follows: "The mechanism involves a vaccine induced immune activation exacerbating an already existing immune dysfunction resulting in an autoimmune or immune activation process that subsequently caused a small fiber neuropathy/fibromyalgia type syndrome." Ex. 63 ("Second Neuenschwander Rep.") at 5.

Dr. Neuenschwander based his opinion regarding Petitioner's correct diagnosis on his emergency medicine experience. Second Neuenschwander Rep. at 1. He opined that Petitioner "has the classic presentation of a patient suffering from SFN" beginning with hypersensitivity to touch and progressing to a pain syndrome. *Id.* Dr. Neuenschwander downplayed the importance of intra-epidermal nerve fiber density testing, noting that the test has a false negative rate in the 10-20% range, and that few SFN patients receive this testing. *Id.* at 2. Ultimately, Dr. Neuenschwander stated that he based his diagnosis of Petitioner on "the fact that a high percentage of patients with fibromyalgia have SFN along with the fact that her clinical picture fits the description of pain caused by SFN." *Id.*

Dr. Neuenschwander concluded his second report by reiterating his opinion that Petitioner was injured by the Tdap vaccine, that her injury has persisted, and that she satisfies all three of the *Althen* prongs. Second Neuenschwander Rep. at 5.

C. Respondent's Expert: Dr. Aaron Levinson, M.D.

Dr. Levinson received his medical degree from the University of Maryland in 1969. Ex. B ("Levinson CV") at 1. Dr. Levinson is currently an emeritus professor of medicine and neurology at the University of Pennsylvania, and formerly served as the Director of the Penn Center for Clinical Immunology at the University of Pennsylvania School of Medicine and Chief of Allergy and Immunology at the Philadelphia Veteran Administration Medical Center. *Id.* at 2. Dr. Levinson is board certified in internal medicine and allergy and clinical immunology. *Id.* In 2011, Dr. Levinson received a Distinguished Service Award from the American Academy of Allergy, Asthma, and Immunology. *Id.* at 3. He served on the editorial board for the Journal of Allergy and Clinical Immunology and Journal of Clinical Immunology and was guest reviewer for a number of publications, including, Clinical Immunology, Journal of Immunology, Annals of Internal Medicine, and Journal of Neuroscience. *Id.* at 4. Dr. Levinson was a consultant to a number of pharmaceutical companies and advisory panels and served on academic committees at the University of Pennsylvania. *Id.* at 4-5. He has delivered a number of lectures at symposiums around the world. *Id.* at 6-9. Dr. Levinson has published over 100 peer-reviewed papers and over 40 book chapters, editorials, and reviews. *Id.* at 10-21.

Dr. Levinson filed three expert reports in this case. Exs. A ("First Levinson Rep."), E, ("Second Levinson Rep."), and H ("Third Levinson Rep.").

Dr. Levinson agreed that Petitioner suffers from fibromyalgia and described Petitioner's symptoms as classic for the disorder. First Levinson Rep. at 6. These symptoms included widespread pain on both sides of the body, neck pain, back and pelvis pain, along with trigger points on physical exam, a feeling of pins and needles, hypersensitivity to touch, a swollen feeling in the hands and feet, headaches, irritable bowel syndrome, fatigue, anxiety, and depression. *Id.* Dr. Levinson opined that Dr. Denio's records suggest Petitioner developed fibromyalgia before vaccination, but because these earlier rheumatology records were not filed, it is impossible to know for sure. *Id.* at 7.

Dr. Levinson disagreed with Dr. Bark that Petitioner either had or was ever diagnosed with ME/CFS. First Levinson Rep. at 7. He cited a 2015 study that developed diagnostic guidelines for this condition. *Id.* at 10.[8] In order to be diagnosed with ME/CFS, a patient must experience the following three symptoms:

> 1. A substantial reduction or impairment in the ability to engage in pre-illness levels of occupational, educational, social, or personal activities that persists for more than 6 months and is accompanied by fatigue, which is often profound, is of new or definite onset (not lifelong), is not the result of ongoing excessive exertion, and is not substantially alleviated by rest;
> 2. Post-exertional malaise; and
> 3. Unrefreshing sleep.
>
> At least one of the following two manifestations is also required:
> 1. Cognitive impairment or
> 2. Orthostatic intolerance
>
> Frequency and severity of symptoms should be assessed. The diagnosis of ME/CFS should be questioned if patients do not have these symptoms at least half of the time with moderate, substantial, or severe intensity.

IOM Criteria at 6. In analyzing these criteria, Dr. Levinson concluded that because cognitive impairment and orthostatic intolerance were not central features in Petitioner's condition, ME/CFS was not an appropriate diagnosis. First Levinson Rep. at 11.

Dr. Levison discussed the components of the Tdap vaccine and noted that "[c]ommon side effects of Tdap include pain and swelling at the injection site, low-grade fever, headache, malaise, abdominal discomfort including nausea, vomiting or diarrhea, myalgias, and lymphadenopathy." First Levinson Rep. at 7. He noted that uncommon side effects include allergic reaction. *Id.*

Dr. Levinson then discussed the aluminum component of the Tdap vaccine. He noted that aluminum is an abundant element that is frequently encountered in the environment. First Levinson Rep. at 8. Average adults ingest 7-9 milligrams of aluminum per day. *Id.* Alum, an aluminum

[8] citing, COMM. ON THE DIAGNOSTIC CRITERIA FOR MYALGIC ENCEPHALOMYELITIS/CHRONIC FATIGUE SYNDROME, INST. OF MED., BEYOND MYALGIC ENCEPHALOMYELITIS/CHRONIC FATIGUE SYNDROME: REDEFINING AN ILLNESS (2015) (filed as Ex. A, Tab 3) ("IOM Criteria").

compound, is added to vaccines in order to boost the immune response. *Id.* He noted that the quantity of aluminum in vaccines is low, and is "miniscule" when compared with the amount of aluminum ingested each day. *Id.* Both the National Vaccine Program Office and the Global Advisory Committee on Vaccine Safety (part of the World Health Organization) have reviewed studies on aluminum-containing vaccines and have determined there is "no evidence of health risks that would require changes to vaccine policy." *Id.* at 9. The Tdap vaccine contains .33 mg of aluminum per dose. *Id.*

Dr. Levinson disagreed with Dr. Bark that the aluminum hydroxide in the vaccine caused the development of Petitioner's fibromyalgia. First Levinson Rep. at 12. He further stated: "I am not aware of any scientific literature that indicates that alum in a species-adjusted dose to that of < 0.33 mg (amount of aluminum hydroxide in a human Tdap dose) induces autoimmune disease in an experimental animal." *Id.* at 13. Dr. Levinson similarly disagreed with Dr. Neuenschwander's assertions about aluminum, opining that he "offers no evidence that toxicity can be induced by the amount of aluminum in a single vaccine." Second Levinson Rep. at 4. Dr. Levinson likewise found Dr. Neuenschwander's theory to be implausible, noting it is unclear "why a single intramuscular injection of an aluminum-containing Tdap vaccine would lead to a chronic persistent ER hyper-stress response that caused oxidative stress in remotely located small somatic fibers and autonomic fibers and not large somatic fibers." *Id.* at 6.

Dr. Levinson also disagreed with Dr. Bark's proposed causal theory. First Levinson Rep. at 13. According to Dr. Levinson, Dr. Bark opined that "the ER hyperstress mechanism induced autoimmunity as a consequence of the so-called unfolded protein response (UPR)." *Id.* He described Dr. Bark's opinion as "very curious" and "quite tangential to this case" because there has been no evidence presented that any of Petitioner's conditions were caused by an autoimmune process. *Id.* He also criticized the medical literature cited by Dr. Bark and noted that none of the literature discussed how the Tdap vaccine could have caused chronic ER stress in Petitioner's tissues. *Id.* at 14-15.

Dr. Levinson concluded his first report by opining as follows:

> First, for the reasons already stated in my report, Dr. Bark has failed to reliably support her vaccine causality theory in this case. Second, she failed to show that Mrs. Ruzicka's chronic debilitating symptoms were a manifestation of an underlying autoimmune disease. Third, she failed to reliably explain how her chronic symptoms might have been caused by aluminum-induced hyperstress-related mechanisms allegedly induced by a single intramuscular injection of Tdap and 4) even if she did suffer from CFS/ME, there is absolutely no evidence that reliably links aluminum to the pathogenic UPR reported in patients with this syndrome.

First Levinson Rep. at 17.

D. Respondent's Expert: Dr. Carlos Rose, M.D., C.I.P.

Dr. Rose received his medical degree from the University of Buenos Aires School of Medicine in Argentina in 1977. Ex. D ("Rose CV") at 1. He completed a residency in internal medicine and a fellowship in adult rheumatology at the University of Buenos Aires Hospital. *Id.* at 5. Dr. Rose then went on to a pediatric residency at Thomas Jefferson University, in Philadelphia, which was followed by a fellowship in pediatric rheumatology at Children's Hospital of Philadelphia, and a year of rotation focused on rheumatology at DuPont Children's Hospital in Wilmington, Delaware. *Id.* at 2. Dr. Rose is board-certified in pediatrics as well as pediatric and adult rheumatology. *Id.* at 3-4, 5-6. He has been a practicing physician for 40 years. Ex. C ("Rose Rep.") at 1.

Dr. Rose filed one expert report in this case. In that report, he agreed that Petitioner suffered from fibromyalgia. Rose Rep. at 8. Dr. Rose described that widespread pain distribution, hyperalgesia, subjective swelling, and paresthesias, are all typical of fibromyalgia. *Id.* at 9. He further noted that Dr. Denio described paresthesias, diffuse myalgia, and arthralgia as symptoms Petitioner had experienced in the distant past. *Id.* He opined that Petitioner's fibromyalgia symptoms "preceded her disease for years." *Id.* at 12.

Fibromyalgia is considered a primary pain syndrome and not an inflammatory disease. Rose Rep. at 9. This point is supported by the fact that the most common treatment modalities for fibromyalgia are Cymbalta and Lyrica, which target pain modulation, as well as cognitive behavioral therapy. *Id.* at 9-10. The mechanisms that are involved in the pathogenesis of fibromyalgia take years to develop, not days or weeks. *Id.* at 12.

Dr. Rose discussed different clinical syndromes associated with hypothyroidism. Rose Rep. at 11. These include rheumatoid arthritis-like disease, pseudogout-like episodes, hyperuricemia-rarely gout, flexor tenosynovitis of the hand, carpal tunnel syndrome, and proximal myopathy. *Id.* In addition, patients with hypothyroidism may also develop "fibromyalgia-like symptoms". *Id.* at 12. Dr. Rose theorized that Petitioner's hypothyroidism contributed to her musculoskeletal symptoms. He stated that "carpal tunnel and other nerve entrapment syndromes associated with acroparesthesia (paresthesia in fingers and toes) are quite typical of hypothyroidism and can be responsible for up to 70% of carpal tunnel syndrome." *Id.*

Ultimately, Dr. Rose opined that Petitioner developed fibromyalgia before her Tdap vaccination, and that there is no plausible relationship between the vaccine and that disease. Rose Rep. at 13.

E. Respondent's Expert: Dr. Lan Zhou, M.D., Ph.D.

Dr. Zhou received his medical degree from Shanghai Medical University in 1989 and his Ph.D. in developmental biology from the University of Cincinnati in 1995. Ex. G ("Zhou CV") at 1. Dr. Zhou is currently a professor of neurology and pathology, and vice chair of research at the Boston University School of Medicine. *Id.* He is board certified in neurology, nerve and muscle pathology, and neuromuscular medicine. *Id.* at 2.

Dr. Zhou filed two expert reports in this case. Exs. F ("First Zhou Rep.") and I ("Second Zhou Rep."). His first report was filed in response to Dr. Neuenschwander. First Zou Rep. In the

report, Dr. Zhou stated that Dr. Neuenschwander's diagnosis of small fiber neuropathy was erroneous. *Id.* at 8. Dr. Zhou opined that diagnosis of SFN should include a combination of signs, symptoms, and diagnostic testing. *Id.* at 7. He discussed several of Petitioner's normal physical exams and that they suggested she did not suffer from SFN. *Id.* Dr. Zhou specifically stated: "While the symptoms and signs may suggest small fiber dysfunction, the exams did not consistently show abnormal sensory findings in the same locations, some of her symptoms were transient and migrating, so … the diagnosis of small fiber neuropathy cannot be established without confirmatory test findings." *Id.* He described intra-epidermal nerve fiber density testing (IENFD) as "the gold standard diagnostic test for small fiber neuropathy." *Id.* at 8. Although Petitioner was offered skin biopsy testing, she refused the test. *Id.* at 8.

Dr. Zhou also opined that there was no causal link between the Tdap vaccine and SFN. First Zhou Rep. at 8-9.

Dr. Zhou discussed Petitioner's history of poorly controlled hypothyroidism. On September 11, 2014, Petitioner's TSH was measured at 78.62 ulU/mL, where a normal result is between 0.27 to 4.2 ulU/mL. First Zhou Rep. at 9; Ex. 2 at 32. Dr. Zhou pointed out that Petitioner's result was 18.7 times higher than the upper normal limit. Further, Dr. Zhou noted that Petitioner's thyroid levels continued to remain elevated. *Id.* at 10. For example, on January 20, 2015, Petitioner's TSH was measured at 26.5 ulU/mL. *Id.*; Ex. 2 at 105. Dr. Zhou stated it is known that hypothyroidism can cause myalgia and fatigue, and sometimes, more severe myopathy. First Zhou Rep. at 10; citing Sindoni et al., *Hypothyroid myopathy: A peculiar clinical presentation of thyroid failure. Review of the literature*, 17 REV ENDOCR METAB DISORD 499-516 (2016) (filed as Ex. F, Tab 7) (hereinafter "Sindoni"). Hypothyroidism can also cause neuropathy, including SFN. First Zhou Rep. at 10; citing Devigili et al., *The diagnostic criteria for small fibre neuropathy: from symptoms to neuropathology*, 131 BRAIN 1912-25 (2008) (filed as Ex. F., Tab 3) (hereinafter "Devigili-1"); Khan & Zhou, *Characterization of Non-Length-Dependent Small-Fiber Sensory Neuropathy*, MUSCLE & NERVE 86-91 (2012) (filed as Ex. F, Tab 8) (hereinafter "Khan & Zhou").

In his second report, Dr. Zhou reiterated that Petitioner did not suffer from small fiber neuropathy, Petitioner's symptoms were not connected to the Tdap vaccine, and that Petitioner's uncontrolled thyroid condition could have caused her symptoms. Second Zhou Rep. at 1.

V. Applicable Law

A. Petitioner's Burden in Vaccine Program Cases

Under the Vaccine Act, when a petitioner suffers an alleged injury that is not listed in the Vaccine Injury Table, a petitioner may demonstrate that she suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

In attempting to establish entitlement to a Vaccine Program award of compensation for an off-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner establish by preponderant evidence that the vaccination she received caused her injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical

sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278.

Under the first prong of *Althen*, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Proof that the proffered medical theory is reasonable, plausible, or possible does not satisfy a petitioner's burden. *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359-60 (Fed. Cir. 2019).

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). However, special masters are "entitled to require some indicia of reliability to support the assertion of the expert witness." *Boatmon*, 941 F.3d at 1360, *quoting Moberly*, 592 F.3d at 1324. Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Hum. Servs.*, 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017); *see also Hock v. Sec'y of Health & Hum. Servs.*, No. 17-168V, 2020 U.S. Claims LEXIS 2202 at *52 (Fed. Cl. Spec. Mstr. Sept. 30, 2020).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause-and-effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs*., 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem*., 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are generally trustworthy because they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions," where "accuracy has an extra premium." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378 (Fed. Cir. 2021) citing *Cucuras*, 993 F.2d at 1528. This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825 at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013), *claim den*., 2020 WL 5641872 (Fed. Cl. Spec. Mstr. Aug. 26, 2020), *rev. den*., 152 Fed. Cl. 782 (2021), *rev'd and remanded*, 34 F.4th 1350 (Fed. Cir. 2022).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475 at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also

Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475 at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825 at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611 at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of her claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (*citing Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted").

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations").

D. Consideration of Medical Literature

Although this decision discusses some but not all of the medical literature in detail, I reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

VI. Analysis

Because Petitioner does not allege an injury listed on the Vaccine Injury Table, her claim is classified as "off-Table." As noted above, to prevail on an "off-Table" claim, Petitioner must prove by preponderant evidence that she suffered an injury and that this injury was caused by the vaccination at issue. *See Capizzano*, 440 F.3d at 1320.

A. Credibility of the Experts

Special masters may consider an expert's background and expertise when weighing that expert's opinion. *See Depena v. Sec'y of Health & Hum. Servs.*, No. 13-675V, 2017 WL 1075101 (Fed. Cl. Spec. Mstr. Feb. 22, 2017), *mot. for rev. denied*, 133 Fed. Cl. 535, 547-48 (2017), *aff'd without op.*, 730 Fed. App'x 938 (Fed. Cir. 2018); *Copenhaver v. Sec'y of Health & Hum. Servs.*,

No. 13-1002V, 2016 WL 3456436 (Fed. Cl. Spec. Mstr. May 31, 2016); *mot. for rev. denied*, 129 Fed. Cl. 176 (2016). "Determinations of credibility, especially of expert opinions, are uniquely within the purview of the special masters." *Gurr v. Sec'y of Health & Human Servs.*, 37 Fed. Cl. 314, 320 (1997) (citing *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993)).

I do not find Petitioner's experts to be persuasive.[9] Dr. Bark repeatedly mischaracterized the medical record and arrived at a diagnosis unsupported by the medical evidence in this case. "An expert opinion is no better than the soundness of the reasons supporting it." *Perreira v. Sec'y of Health & Hum. Servs.*, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994). Their board certifications in general medicine and surgery (Dr. Bark) and emergency medicine (Dr. Neuenschwander) make them generally qualified to opine on medical matters. However, neither Dr. Bark nor Dr. Neuenschwander is a neurologist, a rheumatologist, or an immunologist, the fields at issue in this case regarding a diagnosis of SFN and fibromyalgia, and in assessing causality. In sum, neither expert was persuasive, neither is a medical specialist in case-related fields, and while their causal theories were similar, they provided contradictory evidence on the question of diagnosis. For these reasons, I find the opinions offered by Respondent's experts to be more persuasive than the opinions of Dr. Bark or Dr. Neuenschwander.

B. Petitioner Has Not Carried Her Burden of Proof

As a threshold matter, a petitioner must establish she suffers from the condition for which she seeks compensation. *Broekelschen,* 618 F.3d at 1346. "The function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record as a whole and

---

[9] Both Dr. Bark and Dr. Neuenschwander espouse anti-vaccine views detailed in their CVs. For example, Dr. Bark was a contributing author of a book entitled, Vaccine Epidemic, How Corporate Greed, Biased Science, and Coercive Government Threaten Our Human Rights, Our Health, and Our Children. Bark CV at 3. VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN (Louise Kuo Habakus, et al., eds., 2012). She also participated in the creation of several items that she described in her CV as educational materials. *Id.* at 3-4. The 2015 documentary film entitled "Bought", as well as the "Vaccines Revealed" and "Truth about Vaccines" 2017 documentary series all contain anti-vaccine views. On May 6, 2016, Dr. Bark was a guest on Alex Jones's radio show discussing "Vaccine Injury". CV at 5. She also appeared in a documentary film entitled "The Silent Epidemic: The Untold Story of Vaccines." Bark CV at 6. The summary of this documentary reads as follows: "A factual science based review and evaluation of vaccines and their impact on our health. Experts detail how fraught the widespread use of vaccines is for our current and future generations." *The Silent Epidemic: The Untold Story of Vaccines*, INTERNET MOVIE DATABASE, www.imdb.com /title/tt3290196/ (last visited Oct. 30, 2023). Dr. Neuenschwander is a board member of the Informed Consent Action Network. Neuenschwander CV at 2. This organization dedicates a portion of its website to a "vaccine safety debate," where it invites viewers to "[g]et a cup of tea or coffee, and get ready to finally read the great vaccine debate so you can make a truly informed decision the next time you need to decide whether to vaccinate yourself or your child." *Vaccine Safety Debate*, INFORMED CONSENT ACTION NETWORK, www.icandecide.org/vaccine-safety-debate/ (last visited Oct. 30, 2023). He is a regular speaker for the Medical Academy of Pediatric Special Needs (MAPS), where he has discussed topics that include gut abnormalities, gut-brain-immune connections, and toxicity in autism. *Id.*

the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner]'s injury.'" *Andreu v. Sec'y of Health & Hum. Servs*., 569 F.3d 1367, 1382 (Fed. Cir. 2009) (quoting *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)). "Although the Vaccine Act does not require absolute precision, it does require the petitioner to establish an injury – the Act specifically creates a claim for compensation for 'vaccine-related injury or death.'" *Stillwell v. Sec'y of Health & Hum. Servs*., 118 Fed. Cl. 47, 56 (2014) (quoting 42.U.S.C. § 300aa-11(c)). Accordingly, the Federal Circuit has concluded that it is "appropriate for the special master to first determine what injury, if any, [is] supported by the evidence presented in the record" before applying a causation analysis pursuant to *Althen v. Secretary of Health & Human Services,* 418 F.3d 1274 (Fed. Cir. 2005). *Lombardi v. Sec'y of Health & Hum. Servs*., 656 F.3d 1343, 1351-53 (Fed. Cir. 2011).

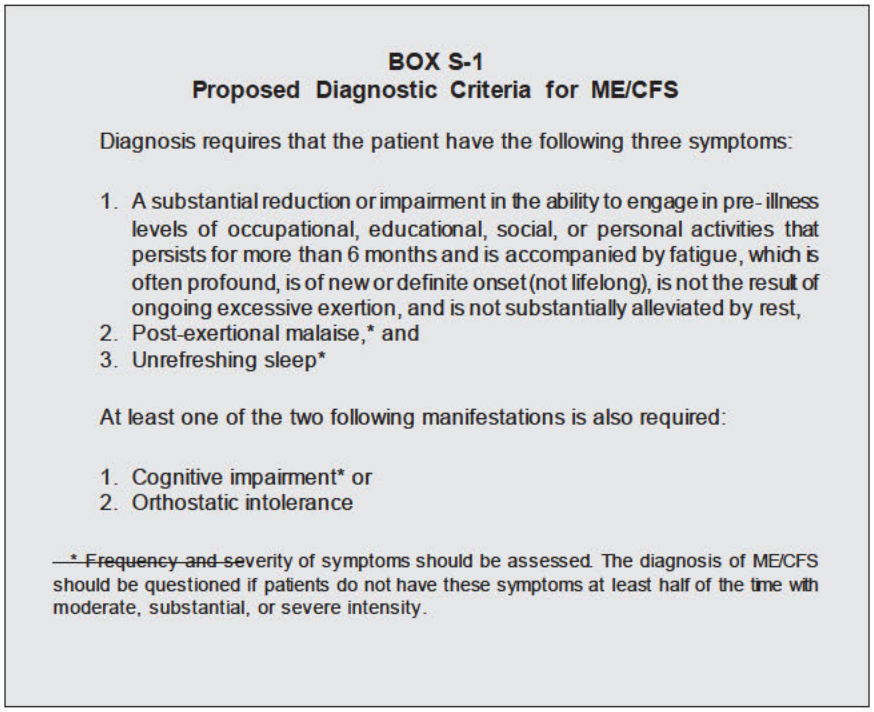
During the course of this case, Petitioner has alleged that she suffers from various conditions, to include fibromyalgia, "post vaccination syndrome," myalgic encephalomyelitis and chronic fatigue syndrome (ME/CFS), and small fiber neuropathy.

1. Petitioner has not Established that She Suffers from ME/CFS or SFN

a. ME/CFS

In her first expert report filed in this case, Petitioner, through her expert Dr. Bark, alleged that she suffered from myalgic encephalomyelitis and chronic fatigue syndrome (ME/CFS). In fact, Dr. Bark contended that "Petitioner has been diagnosed by her treating physicians with a vaccine-induced Myalgic Encephalomyelitis\Chronic Fatigue Syndrome [ME\CFS] and Fibromyalgia." Bark Rep. at 3. This statement is not true in that none of Petitioner's treating physicians diagnosed her with ME/CFS. Petitioner's other expert, Dr. Neuenschwander, opined that "[t]his is not a case of ME/CFIDS as implied by one of you [sic] other experts." First Neuenschwander Rep. at 1. Further, as discussed by Dr. Levinson, Petitioner does not meet the diagnostic criteria for this disorder. First Levinson Rep. at 7.

The Committee on the Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome, the Board on the Health of Select Populations, and the Institute of Medicine published the Proposed Diagnostic Criteria for ME/CFS, reproduced below:



BOX S-1
Proposed Diagnostic Criteria for ME/CFS

Diagnosis requires that the patient have the following three symptoms:

1. A substantial reduction or impairment in the ability to engage in pre-illness levels of occupational, educational, social, or personal activities that persists for more than 6 months and is accompanied by fatigue, which is often profound, is of new or definite onset (not lifelong), is not the result of ongoing excessive exertion, and is not substantially alleviated by rest,
2. Post-exertional malaise,* and
3. Unrefreshing sleep*

At least one of the two following manifestations is also required:

1. Cognitive impairment* or
2. Orthostatic intolerance

~~* Frequency and s~~everity of symptoms should be assessed. The diagnosis of ME/CFS should be questioned if patients do not have these symptoms at least half of the time with moderate, substantial, or severe intensity.

IOM Criteria at 6. While Petitioner did complain about fatigue and impaired sleep, she did not tell her treating physicians that her sleep was unrefreshing. *See, e.g.* Ex. 2 at 144 (On June 3, 2015, Petitioner described that she sleeps 2-3 hours per night, on average). Further, the medical record does not document either cognitive impairment or orthostatic intolerance. As Dr. Levinson opined, "[i]n the final analysis, whereas the petitioner complained about fatigue and at times impaired sleep, cognitive impairment and orthostatic intolerance were not major features of her clinical maladies. Accordingly, she does not fulfill criteria for the diagnosis of ME/CFS." First Levinson Rep. at 11. This is especially true given the admonition in the proposed criteria that "the diagnosis of ME/CFS should be questioned if patients do not have these symptoms at least half of the time with moderate, substantial, or severe intensity." IOM Criteria at 6.

Dr. Bark did not provide any rationale supporting her assertion that Petitioner suffers from ME/CFS. She did not discuss the diagnostic criteria. Nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for rev. denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. Appx. 999 (Fed. Cir. 2013). Petitioner has not presented preponderant evidence that she suffers from ME/CFS.

b. SFN

Small fiber neuropathies are disorders that damage thinly myelinated and unmyelinated nerve fibers. Patients with small fiber neuropathy often complain of pain, burning, tingling, and numbness. First Zhou Rep. at 6. There is not a standardized set of diagnostic criteria for SFN,

however diagnosis should include an assessment of a patient's symptoms, signs, and diagnostic test findings. *Id.* at 7. "Sensory symptoms alone should not be considered a reliable screening feature." Devigili et al., *Diagnostic criteria for small fibre neuropathy in clinical practice and research*, 142 BRAIN 3728-36 (2019) (filed as Ex. F, Tab 5) (hereinafter "Devigili-2"). Skin biopsy with quantification of intraepidermal nerve fiber density is the most reliable test to confirm a SFN diagnosis. Dr. Zhou described it as "the gold standard diagnostic test for small fiber neuropathy with a high diagnostic efficiency of 88%." First Zhou Rep. at 8.

Petitioner's sensory examinations failed to detect the numbness that she reported, and further, the exams did not consistently show abnormal findings. For example, on September 17, 2014, Petitioner reported tingling and numbness in the feet and hands. However, the sensory exam conducted by Dr. Bobek was normal. Ex. 2 at 47. Two days later, Dr. Bobek detected allodynia in her hands, proximal thighs, and trunk. *Id.* at 56. However, he still did not detect numbness. *Id.* On November 3, 2014, Petitioner reported paresthesias, however the physical exam conducted by Dr. Bobek was normal except that he documented "some tenderness with palpation of the ulnar groove in the medial left elbow area." Ex. 2 at 88. Two days later, on November 5, 2014, Dr. Alario and Dr. Roy noted hyperesthesia in the torso and lateral thigh, however, they documented that her sensation was "normal to pin", meaning that she had a normal pinprick test. Ex. 3 at 6. On March 25, 2015, Dr. Scott Friedenberg, a neurologist, conducted a neurologic exam that was entirely normal. Ex. 3 at 53-54.

In discussing these findings, Dr. Zhou noted that numbness has never been detected at any medical visit, "which is atypical for significant small fiber degeneration." First Zhou Rep. at 7. He summarized by opining: "While the symptoms and signs may suggest small fiber dysfunction, the exams did not consistently show abnormal sensory findings in the same locations, some of her symptoms were transient and migrating, so in a case like this, the diagnosis of small fiber neuropathy cannot be established without confirmatory test findings." *Id.* Indeed, none of Petitioner's treating physicians diagnosed her with SFN, although several doctors did suggest that Petitioner rule out other possible disorders through nerve fiber testing. Ex. 3 at 54; Ex. 21 at 7. There is no indication in the record that this testing was ever performed.

Dr. Neuenschwander based his diagnosis of Petitioner on "the fact that a high percentage of patients with fibromyalgia have SFN along with the fact that her clinical picture fits the description of pain caused by SFN." Second Neuenschwander Rep. at 2. Dr. Neuenschwander, who is not a neurologist, did not discuss any of Petitioner's physical examinations and how they did or did not support his proposed diagnosis. He downplayed the importance of IENFD testing in an unpersuasive manner by noting that many patients with SFN are not appropriately evaluated, and that the only way to firmly establish Petitioner's Tdap vaccine as the cause of her condition would have been to conduct nerve fiber density testing before and after vaccination. *Id.*

Ultimately, none of Petitioner's treating doctors diagnosed her with SFN, her physical examinations were inconsistent and never documented numbness, and IENFD testing was not performed. Because of this, I agree with Dr. Zhou that Petitioner has not established by preponderant evidence that she suffers from small fiber neuropathy. Second Zhou Rep. at 1.

2. Post Vaccination Syndrome

It is questionable whether "post vaccination syndrome" constitutes a cognizable injury in the Vaccine Program. No treating physician or expert has provided a set of diagnostic criteria for "post vaccination syndrome" or discussed how Petitioner's symptoms met these criteria. Accordingly, it is not possible to assess whether this is a condition that Petitioner developed. *Broekelschen,* 618 F.3d at 1346; *Lombardi*, 656 F.3d at 1352-1353 ("under *Broekelschen*, identification of a petitioner's injury is a prerequisite to an *Althen* analysis of causation," and "the statute places the burden on the petitioner to make a showing of at least one defined and recognized injury").

Aside from my concerns with the vagueness of this proposed condition, I find that the symptoms Petitioner experienced are best explained by her diagnosis of fibromyalgia.

3. Petitioner's Fibromyalgia Diagnosis is Supported by the Record

Fibromyalgia is a pain syndrome characterized by widespread pain distribution, tenderness, hyperalgesia, subjective swelling, and paresthesias. Rose Rep. at 9; Leslie Crofford, *Fibromyalgia*, *in* HARRISON'S PRINCIPLES OF INTERNAL MEDICINE (J. Larry Jameson, et al., eds., 20th ed. 2018) (filed as Ex. A, Tab 1). Dr. Levinson opined that Petitioner's symptoms of widespread pain involving both sides of the body, pins and needles, hypersensitivity to touch, subjective feelings of swelling, headaches, irritable bowel syndrome, tiredness, anxiety, and depression were all "classic for the diagnosis of fibromyalgia." First Levinson Rep. at 6.

Petitioner's treating rheumatologist, Dr. Denio, diagnosed her with fibromyalgia. Ex. 3 at 31. All the experts (except Dr. Bark) agree with this diagnosis. Dr. Rose, a rheumatologist, opined that "[b]ased on the 1990 American College of Rheumatology diagnostic criteria for fibromyalgia (1) as well as the 2012 and 2016 revisions there is no doubt in my mind that on 1/20/2015 when she was evaluated by Dr. Denio she could be classified as suffering from this painful condition." Rose Rep. at 8. Accordingly, I find Petitioner's fibromyalgia diagnosis is supported by preponderant evidence.

4. *Althen* Prong One

Under *Althen* prong one, a petitioner must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Proof that the proffered medical theory is plausible or possible does not satisfy a petitioner's burden. *Boatmon v. Sec'y of Health & Hum. Servs*., 941 F.3d 1351, 1359-60 (Fed. Cir. Nov. 7, 2019).

A petitioner may satisfy this prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). However, special masters are "entitled to require some indicia of reliability to

support the assertion of the expert witness." *Boatmon*, 941 F.3d at 1360, *quoting Moberly*, 592 F.3d at 1324. Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Hum. Servs.*, 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017); *see also Hock v. Sec'y of Health & Hum. Servs.*, No. 17-168V, 2020 U.S. Claims LEXIS 2202 at *52 (Fed. Cl. Spec. Mstr. Sept. 30, 2020). Because I have concluded that Petitioner's correct diagnosis is fibromyalgia, I will consider whether Petitioner has presented preponderant evidence that the Tdap vaccine can cause that condition.

Dr. Bark and Dr. Neuenschwander propose similar theories of causation: the Tdap vaccine led Petitioner to develop endoplasmic reticulum stress, which in turn resulted in chronic immune overactivation, which caused her condition (Dr. Bark) versus chronic activation of the cell danger response through an overreaction to the Tdap vaccine (Dr. Neuenschwander).

Petitioner's theory is vague and unsupported. According to Dr. Bark, "ER HyperStress results from a combination of genetics risk factors petitioner had, coupled with environmental exposures (aluminum hydroxy), which together can cause cellular death and pathological outcomes experienced by petitioner." Bark Rep. at 3. However, as noted by Dr. Levinson, Dr. Bark did not explain which cells were killed in Petitioner's tissues or how the death of these cells caused her condition. First Levinson Rep. at 13. Dr. Neuenschwander's favored theory, "immune over-activation and subsequent exacerbation of pre-existing autoimmunity," (First Neuenschwander Rep. at 5) aside from the unsupported assumption that Petitioner experienced an immune over-activation, does not explain what caused the persistence of the oxidative stress or how that took place. In fact, nowhere did either of Petitioner's experts explain how the Tdap vaccine resulted in Petitioner's *chronic* condition.

Further reducing the persuasiveness of Petitioner's causal theory is its "aluminum toxicity" component. While Petitioner filed medical literature suggesting that under some circumstances, aluminum can negatively impact cell function, "[t]here is no reason to believe that the effect of aluminum on vitro cultured astrocytes, neuroblastoma cells or hepatic cells translates to the alleged in vivo effects of a single injection of 0.33 mg of aluminum hydroxide into the deltoid muscle of a human." First Levinson Rep. at 15. Petitioner's medical literature even illustrates the low level of aluminum exposure from vaccines when compared with other sources, to include "air inhalation":

Table 2 Al exposure from alternate source (adapted from Yokel et al. 2008)

Source	**Al exposure**
Antacids	5,000,000 μg/day
Air inhalation	4–20 μg/day
Industrial air inhalation	25,000 μg/day

Antiperspirants	70,000 µg/day
Cigarettes	500–2,000 µg/cigarette
Vaccines	1–8 µg/day
Allergy immunotherapy	7–40 µg/day

Sung Han et al., *How aluminum, an intracellular ROS generator promotes hepatic and neurological diseases: the metabolic tale*, 29 CELL BIOLOGY & TOXICOLOGY 75-84, 76 (2013) (filed as Ex. 9). Dr. Neuenschwander seemingly eschewed a theory involving direct toxicity of aluminum, noting "I will not press this as a cause, because there is a lack of direct evidence in Francis' situation." First Neuenschwander Rep. at 5.

I further note that the autoimmune syndrome induced by adjuvants or "ASIA" theory has not been found to be sufficient to satisfy *Althen* prong one. *See, e.g., Monzon v. Sec'y of Health & Hum. Servs.,* No. 17-1055V, 2021 WL 2711289, at *8 n.6 (Fed. Cl. Spec. Mstr. June 2, 2021); *Garner v. Sec'y of Health & Hum. Servs.,* No. 15-0063V, 2017 WL 1713184, at *15 (Fed. Cl. Spec. Mstr. Mar. 24, 2017); *Johnson v. Sec'y of Health & Hum. Servs.,* No. 10-0578V, 2016 WL 4917548, at *8-9 (Fed. Cl. Spec. Mstr. Aug. 18, 2016) (describing this theory as overbroad, generalized, and vague and finding this expansive theory logically unpersuasive); *Morris v. Sec'y of Health & Hum. Servs.,* No. 12-415V, 2016 WL 3022141, at *12 (Fed. Cl. Spec. Mstr. Apr. 1, 2016) (discussing lack of reliability of ASIA theory); *Rowan v. Sec'y of Health & Hum. Servs.,* No. 10-272V, 2014 WL 7465661, at *16 (Fed. Cl. Spec. Mstr. Dec. 8, 2014), *mot. for review den'd*, 2015 WL 3562409 (Fed. Cl. May 18, 2015); *D'Angiolini v. Sec'y of Health & Hum. Servs.*, No. 99-578V, 2014 WL 1678145, at *60 (Fed. Cl. Spec. Mstr. Mar. 27, 2014), *mot. for review den'd*, 122 Fed. Cl. 86 (2015), *aff'd*, 645 F. App'x 1002 (Fed. Cir. 2016).

I additionally find that Petitioner's prong one showing is deficient because fibromyalgia is generally not considered to be an autoimmune disease, and thus is unlikely to result from vaccination. Rose Rep. at 9, 12-13; First Levinson Rep. at 13; *see also*, *Mattus-Lang v. Sec'y of Health & Hum. Servs.*, No. 15-113V, 2022 WL 4242140 (Fed. Cl. Spec. Mstr. Aug. 31, 2022) (finding insufficient evidence that a child's seizures had an autoimmune etiology, and therefore determining they could not be vaccine caused); *H.C. v. Sec'y of Health & Hum. Servs.*, No. 16-4V, 2022 WL 2825395 (Fed. Cl. Spec. Mstr. May 9, 2022) (concluding that because Ramsay Hunt is not an autoimmune disease, molecular mimicry was not an applicable *Althen* prong one theory); *McKown v. Sec'y of Health & Hum. Servs.*, No. 15-1451V, 2019 WL 4072113 (Fed. Cl. Spec. Mstr. Jul. 15, 2019) (finding that POTS is usually not an autoimmune condition "greatly reducing the likelihood that a vaccine could initiate an autoimmune process sufficient to cause it."). The point that fibromyalgia does not have an autoimmune etiology is supported by the common therapies for the condition, which include cognitive behavioral therapy, as well as Cymbalta and Lyrica, therapies which target pain modulation, as opposed to anti-inflammatories or immunosuppressing drugs. Rose Rep. at 9-10, 13.

Ultimately, and based on the foregoing, Petitioner has not provided preponderant evidence in support of the first *Althen* prong.

5. *Althen* Prong Two[10]

Althen prong two requires Petitioner to establish a logical sequence of cause and effect demonstrating that the vaccination did cause her condition. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause-and-effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

In weighing evidence, special masters are expected to consider the views of treating doctors. *Capizzano*, 440 F.3d at 1326. The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom they are diagnosing. *See McCulloch v. Sec'y of Health & Hum. Servs.*, No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015).

Dr. Bobek, Petitioner's PCP, diagnosed her with a reaction to vaccination. Ex. 2 at 18. Petitioner's rheumatologist, Dr. Denio, noted that Petitioner's fibromyalgia "appears to have been triggered by a reaction to a Tdap vaccine last July." Ex. 3 at 31. Several other doctors were less committal. For example, Dr. Friedenberg opined that Petitioner had experienced "many years of multiple multifocal neurologic symptoms without etiology identified" and then questioned whether her symptoms were caused by the Tdap vaccine. Ex. 3 at 53. Dr. Preston stated that the "[n]ew onset of GERD symptoms [was] unlikely related to vaccination." Ex. 3 at 23.

Although several of Petitioner's treating physicians linked the Tdap vaccine with her condition, I am not obliged to adopt the same view. *See* 42 U.S.C. §§ 300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted."). Dr. Bobek and Dr. Denio do not provide a rationale for their opinions, which renders them less persuasive. Ultimately,

[10] I note that there is some evidence in the medical records that Petitioner had symptoms consistent with fibromyalgia long before vaccination. On January 20, 2015, Petitioner visited Dr. Denio, who documented that "[t]he patient has been to Rheumatology a couple of times before variously for some diffuse myalgias and arthralgias, the last time in 2002 for some paresthesias in the left hand thought to be on the basis of carpal tunnel syndrome, although the nerve conduction testing at that time was negative." Ex. 3 at 32. On March 25, 2015, Dr. Friedenberg documented that Petitioner had experienced "many years of multiple multifocal neurologic symptoms without etiology identified, sx ppt by recent vaccine? And her flare ups of disease are short lived in past, with vaccination sx have persisted." Ex. 3 at 53. Petitioner was ultimately unable to produce these prior rheumatology records. Accordingly, Dr. Rose opined: "I cannot offer more details regarding the precise time of onset of her fibromyalgia, although it appears to be a problem in her for a long time." Rose Rep. at 8. Although the note in the medical records from Dr. Denio and Dr. Friedenberg constitutes some evidence that Petitioner may have developed fibromyalgia in the past, the absence of these records prevents further meaningful analysis.

while I have considered these opinions in my analysis of Petitioner's case, I find that this evidence does not preponderantly establish that the Tdap vaccine did cause Petitioner's condition.

Additionally, several components of Petitioner's case diminish the persuasiveness of her showing. For instance, Petitioner's theory of the case emphasizes the fact that she had a prior severe adverse reaction to the Tdap vaccine, and that this, in part, caused her to have "a systemic and autoimmune response to the [July 29, 2014] Tdap vaccine." (Pet'r's Mot. at 19; *see also*, Bark Rep. at 3, noting that Petitioner's prior reaction to the prior Tdap vaccine was "serious"). For reasons that are unclear, Petitioner filed the package insert for the Pediarix vaccine, the formulation administered to infants and young children. Ex. 25. That package insert describes that an example of a severe allergic reaction is anaphylaxis. Ex. 25 at 1. Petitioner did not experience anaphylaxis post vaccination. Dr. Levinson described that common side effects of the Tdap vaccine include "pain and swelling at the injection site, low-grade fever, headache, malaise, abdominal discomfort including nausea, vomiting or diarrhea, myalgias, and lymphadenopathy." First Levinson Rep. at 7. Petitioner did experience these symptoms; accordingly, her prior reaction should not be characterized as severe or serious.

Further, there is no indication that Petitioner's condition was caused by an autoimmune process. When measured around November of 2014, her ESR was normal and her ANA was negative. Ex. 3 at 4. These results do not provide support for Dr. Bark's and Dr. Neuenschwander's theories of robust and chronic immune activation. As Dr. Levinson stated, "[t]here is not a single diagnostic immunological test result in her medical records (including biomarkers of underling inflammation like erythrocyte sedimentation rate and C-reactive protein) that suggested an underlying autoimmune or inflammatory process other than her pre-existing thyroiditis." Second Levinson Rep. at 5. Petitioner has not presented preponderant evidence in support of *Althen* prong two.

6. *Althen* Prong Three

Althen prong three requires a petitioner to establish a "proximate temporal relationship" between her condition and the vaccine she received. *Althen*, 418 F.3d at 1281. Petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.,* 539 F.3d 1347, 1352 (Fed. Cir. 2008).

The timing prong contains two parts. First, Petitioner must establish the "timeframe for which it is medically acceptable to infer causation" and second, she must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec'y of Health & Hum. Servs.,* 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013).

Because *Althen* prong three coincides with *Althen* prong one, Petitioner's inability to meet her burden demonstrating how the Tdap vaccine can cause fibromyalgia effectively precludes her from being able to meet her burden under the third *Althen* prong. Thus, because I have found that Petitioner did not offer a sound and reliable theory of causation, she cannot demonstrate that her condition arose in a medically acceptable timeframe pursuant to that theory. Even assuming that

Petitioner satisfied *Althen* prong three, that alone would not satisfy Petitioner's overall burden of proof. *Veryzer v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 344, 356 (2011) (explaining that a "temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury.").

However, in this particular case, Petitioner's showing with respect to the third *Althen* prong is deficient. Dr. Bark briefly discussed the timing element in her expert report.

> In meeting Althen Three, by examining the timing of the exposure and the timing of the onset of the injuries, these factors combined would be inconsistent with causation for any other alternative theory of injury. In other words, it is more likely than not, the TDaP caused the injury in this case because of the dosing and exposure to the toxins, no other intervening cause identified, and because of the proximate relationship between vaccination and injury (less than 48 hours). *Pet.'s Exh. 1 & 2.* Therefore, it is impossible in this case to rule out the TDaP vaccination, as the cause of the injuries from the antigen and aluminum hydroxide found in the vaccine.

Bark Rep. at 2. Dr. Bark opined that because Petitioner's onset of symptoms began 48 hours after vaccination and no other source of injury has been identified, the vaccine must have caused her condition. She provides no other rationale for her opinion, except to mention "dosing and exposure to the toxins." She did not discuss how this timing was appropriate given her theory of causation. Similarly, Dr. Neuenschwander did not discuss an appropriate timeframe for his theory of chronic activation of the danger cell response except to note that "[t]he events clearly are temporally linked to her Tdap vaccine." Second Neuenschwander Rep. at 5. The Federal Circuit has explained that "[a]lthough probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." *Althen*, 418 F.3d at 1278 (citing *Grant*, 956 F.2d at 1149).

In opining that Petitioner has not satisfied the third *Althen* prong, Dr. Rose noted that the pathogenesis of fibromyalgia likely involves "alterations of neurobiological pathways affecting the central nervous system, the terminal nerve fiber density in the skin as well as genetic variants of pain receptors." Rose Rep. at 9. He persuasively opined that these conditions take time to develop and would not occur in days or weeks. He stated that "[i]t is important to understand that the non-genetic abnormalities involving central nervous system connectivity, increased number of sensory fibers and the like need time to develop and are very likely to begin manifesting as pain syndromes over the years in individuals like Ms. Ruzicka." *Id.* at 11.

Based on the above, I find that Petitioner has not presented preponderant evidence in support of the timeframe for which it is medically acceptable to infer causation. She has not met *Althen* prong three.

VII. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, the affidavits, as well as the experts' opinions and medical literature, I conclude that

Petitioner has not shown by preponderant evidence that she is entitled to compensation under the Vaccine Act. **Her petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**[11]

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master

[11] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by each filing (either jointly or separately) a notice renouncing their right to seek review.